

K010346

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY - 2 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact: James A. Lee, Ph.D.
Regulatory Affairs Specialist

Device Identification: Common Name:
Tissue Morcellator

Trade Name: (optional)
KSEA SAWAHLE Electromechanical Morcellator

Indication: These instruments are intended for use by qualified surgeons during general surgery endoscopic procedures, and gynecological endoscopic surgical procedures, including removal/morcellation of myomata.

Device Description: The KSEA SAWAHLE Electromechanical Morcellator in conjunction with the UNIDRIVE II control unit is a motorized, reusable surgical device system, intended for the morcellation and removal of tissue during endoscopic laparoscopic surgical procedures by qualified surgeons.

Substantial Equivalence: The KSEA SAWAHLE Electromechanical Morcellator is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA SAWAHLE Electromechanical Morcellator and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: _____

James A. Lee, Ph.D.
Regulatory Affairs Specialist

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 2 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

James A. Lee, Ph.D.
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230

Re: K010346

Trade Name: KSEA SAWAHLE Electromechanical Morcellator

Classification Regulation Name and Number: Gynecologic Laparoscope and Accessories
884.1720

Laparoscope, General and Plastic Surgery
876.1500

Regulatory Class: II

Product Code: HET, GCJ

Dated: February 2, 2001

Received: February 5, 2001

Dear Dr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not yet assigned K010346

Device Name: KSEA SAWAHLE Electromechanical Morcellator

Indication for Use: These instruments are intended for use by qualified surgeons during general surgery endoscopic procedures, and gynecological endoscopic surgical procedures, including removal/morcellation of myomata.

B. Mitchell MD JRCM

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010346

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)